kubtec

K083510

JAN - 8 2009

510 (k) Summary

Date Prepared [21 CFR 807.92(a)(1)]

11/21/08

Submitter's Information [21 CFR 807.92(a)(1)]

This 510(k) is being submitted by Joseph Azary on behalf of KUB Technologies, Inc.

Submitter / Regulatory Consultant:
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Manufacturer:
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FDA Establishment Registration# Pending

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

The device trade names are:

- XPERT Specimen Radiography System
- XPERT 20

Specimen X-Ray System / Cabinet

Class II, Product Code MWP, 21 CFR 892.1680

Predicate Device [21 CFR 807.92(a)(3)]

- XPERT 40 (K071233)

Description of the Device [21 CFR 807.92(a)(4)]

The XPERT Specimen Radiography System is a self contained, shielded cabinet x-ray system designed to meet imaging requirements for surgically excised and needle core biopsies. This device does not expose the patient to radiation, it is used for biopsy tissue samples only.

The system design features an x-ray source that produces a high resolution, 5 -45 micron focal spot. The control system, coupled with a touch panel screen for operator interface.

The XPERT system features a DICOM 3.0 compliant DIGICOM computer and software application. The DIGICOM enables the display and analysis of x-ray images, either live (real time) or previously captured, and the storage and transmission of these imagines to the PACS.

Intended Use [21 CFR 807.92(a)(5)]

Provide digital x-ray images of harvested tissue specimens from various anatomical regions in order to provide rapid verification that the correct tissue has been excised during the biopsy procedure.

Technological Characteristics [21 CFR 807.92(a)(6)]

The device is substantially equivalent to the predicate device based on a comparison on physical and performance characteristics.

Performance Data [21 CFR 807.92(b)(1)]

The subject device complies electrical and radiation safety requirements and utilizes software that has been validated. The subject device represents a minor modification to the predicate device.

Conclusion [21 CFR 807.92(b)(3)]

We believe the changes are minor and conclude that the subject devices are as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 8 2009

KUB Technologies, Inc.
% Mr. Joseph Azary
Regulatory Consultant
Orchid Design Orthopedic Solutions
80 Shelton Technology Center
SHELTON CT 06484

Re: K083510
Trade/Device Name: Kubtec XPERT 20
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: November 21, 2008
Received: November 26, 2008

Dear Mr. Azary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083510

Device Name: Kubtec XPERT 20

Indications For Use:

Provide digital x-ray images of harvested tissue specimens from various anatomical regions in order to provide rapid verification that the correct tissue has been excised during the biopsy procedure.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083510